

REMARKS

Claims 1-48 are now pending. Claims 1, 4-7, 11-14, 18, 21, 22, 31 and 32 are amended; and claims 35-48 are added herein. Support for the amendments can be found at, for example, col. 4, lines 51-57; col. 6, lines 3-7; col. 6, lines 51-58; col. 7, lines 14-29; and col. 7, lines 42-50.

A first, non-final Office Action was issued on November 13, 2002. In response to this Office Action, an Amendment was timely filed on May 13, 2003, together with a three-month Petition for Extension of Time. Subsequently, a Patent Office communication was issued on June 17, 2003 indicating that the May 13, 2003 Amendment will not be entered and indicating that the period for reply expires six months from the mailing date of the Final Rejection. However, a Final Rejection has not been issued in the above-identified patent application, and no basis has been set forth for refusing entry of the Amendment before Final Rejection. Thus, the May 13, 2003 Amendment should be entered and the June 17, 2003 Patent Office communication should be withdrawn in favor of a new Patent Office communication setting forth a due date for response.

However, in an effort to address the issues raised in the June 17, 2003 Patent Office communication, and thereby expedite allowance, the present Supplemental Amendment is being filed. It is respectfully submitted that for the reasons discussed below, the present Supplemental Amendment places the application in condition for allowance.

In the November 13, 2002 Office Action, the application was objected to for failing to contain a Sequence Listing. In the May 13, 2003 Amendment, the paper copy of the Sequence Listing was replaced and the Patent Office was requested to transfer the computer-readable form from the application that issued as U.S. Patent No. 5,817,465. Therefore, the objection should be reconsidered and withdrawn.

In the November 13, 2002 Office Action, claims 1-34 were also rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-18 of

U.S. Patent No. 5,654,143. As indicated in the June 17, 2003, Patent Office communication, this rejection has been withdrawn in view of the Terminal Disclaimer filed May 13, 2003.

Claims 1-34 are rejected under 35 U.S.C. §251 as being broadened in a reissue application filed outside the two-year statutory period. Applicants respectfully traverse the rejection.

As noted by the Examiner, 35 U.S.C. §251 indicates that "[n]o reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." It is respectfully submitted that the phrase "the original patent" clearly refers to the patent being reissued, not to the first patent obtained in a family of patents.

In the present case, the patent being reissued is U.S. Patent No. 5,817,465 ("the 465 patent"), which was issued on October 6, 1998. Since the reissue application was filed on October 6, 2000, which is within two years of the issue date of the 465 patent, filing claims enlarging the scope is clearly authorized under 35 U.S.C. §251.

In the November 13, 2002 Office Action and the June 17, 2003 Patent Office communication, it is argued that "the original patent" refers to the first patent that issued in the patent family. No authority for such a position has been identified. Instead, it is merely indicated that the error in the patent set forth in the Reissue Declaration was present in the first patent to issue in the patent family, U.S. Patent No. 5,654,143 ("the 143 patent"), which is clearly incorrect. The 465 patent contains the phrase "obtaining a starting solution by adding to a container comprising the sample ..." (emphasis added). The claims of the 143 patent do not contain this phrase. In particular, the corresponding phrase of the 143 patent does not contain the term "comprising."¹ Thus, the claims of the 143 patent clearly do not contain the error set forth in the Reissue Declaration.

¹ Claim 1 is amended herein to delete the term "comprising." This Amendment merely deletes a misplaced term. It does not in any way change the scope of claim 1.

Furthermore, from reading the entirety of 35 U.S.C. §251 and §252, it is clear that the phrase "the original patent" refers to the patent being reissued, not the first patent in a patent family. In particular, the first paragraph of §251 states that "the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent." The reissue patent clearly does not get the patent term of the first patent in the patent family, which in this case is several years longer in view of the transitional procedures that are available to applications filed before June 6, 1995. Instead, it gets the term of the patent that is being reissued, i.e., "the original patent." Similarly, §252 recites that "[t]he surrender of the original patent shall take effect upon the issue of the reissued patent." There is clearly no requirement that the first patent in a patent family be surrendered to obtain reissue of another patent in that patent family. Thus, the phrase "the original patent" is clearly referring to the patent being reissued.

In addition, a review of 37 C.F.R. §1.171-§1.179 also makes clear that the phrase "the original patent" refers to the patent being reissued. See, for example, §1.178(a), which recites that "[t]he application for a reissue should be accompanied by either an offer to surrender the original patent, or the original patent itself, or if the original is lost or inaccessible, by a statement to that effect." This reference to "the original patent" clearly refers to the patent being reissued, and does not refer to an earlier patent in a patent family. See also §1.175(a)(1), which recites that the Reissue Declaration must state that "[t]he applicant believes the original patent to be wholly or partly inoperative or invalid." In this case, the Applicants have not stated nor do they need to state that the 143 patent is wholly or partly inoperative or invalid.

It is further noted that in a November 25, 2003, discussion with Mr. Joseph Narcavage of the Office of Patent Legal Administration, he confirmed that the phrase "the original

patent" refers to the patent being reissued. Thus, it is respectfully submitted that the reissue rejection should be reconsidered and withdrawn.

Claims 1-4, 7, 11, 12, 14, 18-23 and 26-34 are rejected under 35 U.S.C. §102 over Myers et al. Applicants respectfully traverse the rejection.

Claims 1 and 22 have each been amended to recite that "after step a), all steps are performed without subsequent addition of any ingredients." Myers does not teach or suggest such a method. In contrast, Myers teaches, at page 7662, right column, in the paragraph entitled "RT/PCR Coupled Reactions," adding a solution containing various components including a primer "[f]ollowing the RT [reverse transcription] reaction." Thus, Myers clearly fails to teach a process in which ingredients are not added after the formation of the starting solution as recited in claims 1 and 22.

Myers does not teach each and every feature of the invention of claims 1 and 22. Claims 2-4, 7, 11, 12, 14, 18-21, 23 and 26-34 ultimately depend from either claim 1 or claim 22. Therefore, the rejection of these claims under 35 U.S.C. §102 over Myers should be reconsidered and withdrawn.

Claims 1, 3, 4, 8-12, 14, 19, 22-25 and 27-34 are rejected under 35 U.S.C. §102 over Sellner et al. Applicants respectfully traverse the rejection.

Claim 1 has been amended to recite "d) bringing the solution obtained in c) to a predetermined temperature from 45° to 75°C and maintaining said temperature for sufficient time whereby a first cDNA strand is synthesized and a RNA-cDNA heteroduplex is formed." In addition, claim 22 has been amended to recite, at step c, "permitting the first primer to hybridize with the RNA in said solution, followed by synthesis, at a temperature from 45° to 75°C, of a first cDNA strand, thus forming an RNA-cDNA heteroduplex." Sellner does not teach synthesis of a first cDNA strand at a temperature from 45° to 75°C, as recited in claims 1 and 22. In contrast, Sellner teaches synthesizing the first cDNA strand (i.e., conducting RT) at 42°C.

Sellner does not teach each and every feature of claims 1 and 22. Claims 3, 4, 8-12, 4, 19, 23-25 and 27-34 ultimately depend from either claim 1 or claim 22. Therefore, the rejection of these claims under 35 U.S.C. §102 over Sellner should be reconsidered and withdrawn.

Claims 2, 5-7, 13, 18, 20, 21 and 26 are rejected under 35 U.S.C. §103 over Sellner in view of Shimomaye et al. Applicants respectfully traverse the rejection.

The claims rejected on this basis each depend from either claim 1 or claim 22. As discussed above, Sellner does not teach or suggest the invention of claims 1 or 22.

Shimomaye is directed to a method for sequencing RNA in which the RNA template is denatured with the radioactive oligonucleotide at 100°C for 3 minutes and allowed to anneal for 30 minutes at 42°C. Page 26, col. 1. The annealed mixture prepared in this way is then mixed with a reverse transcriptase and a dideoxynucleotide mixture to form a mixture that is then incubated to conduct the sequencing reaction. Page 26, col. 1. As indicated in the Abstract, Shimomaye teaches that the simplest way to overcome template secondary structure is to conduct this sequencing reaction above 47°C. However, this teaching cannot properly be combined with Sellner in order to achieve the present invention.

In particular, the method described in Shimomaye specifically requires pre-annealing of the oligonucleotide primer for 30 minutes at 42°C before the annealed mixture is mixed with the reverse transcriptase. In addition, conducting this annealing step after mixing the RNA with the reverse transcriptase would defeat the purpose of the invention described in Shimomaye since the reverse transcription would begin immediately after annealing at 42°C if the reverse transcriptase was present during the annealing step. As a result, the advantage achieved by conducting the sequencing reaction at a temperature above 47°C would be lost. Thus, any proper combination of Shimomaye with Sellner would result in a process in which the primer is annealed to the RNA before the RNA is mixed with the reverse transcriptase. Therefore, any proper combination of these two references would not result in a method

according to claims 1 and 22, in which the first primer is hybridized with the RNA in the solution formed in step a of each of claims 1 and 22, wherein this solution contains the reverse transcriptase.

In rejecting the claims over Sellner, the Patent Office is interpreting the term "bringing" as not necessarily involving a temperature change. This interpretation is correct, as reflected by the clear teachings in the specification that (1) RNA denaturation and first cDNA strand synthesis and (2) second primer hybridization and second cDNA strand synthesis can each be conducted at the same temperature. See col. 4, lines 53-57; col. 6, lines 3-7; and col. 7, lines 23-29 and 42-50. In responding to the rejection over Sellner in view of Shimomaye, claim 1 is amended to add hybridizing step c. This step recites "bringing the solution obtained in b) to a predetermined temperature" in order to allow for the possibility of changing the temperature. However, as with the other instances of the term "bringing," the hybridization step should not be interpreted as requiring a temperature change. See col. 5, lines 18-20, which indicates that in embodiments of the invention the 3' primer, i.e., the first primer, is "capable of hybridizing with the RNA at the chosen denaturation temperature."

Sellner cannot be combined with Shimomaye in order to achieve the invention of claims 1 or 22. Therefore, the rejection over these references should be reconsidered and withdrawn.

Claims 35-48 have been added to further define the invention. Claim 35 depends from claim 22 and claim 36 depends from claim 1. Therefore, claims 35 and 36 are patentable for at least the reasons discussed above with regard to the claims on which they depend.

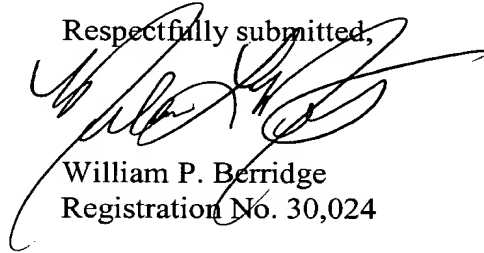
Claim 37 is an independent claim. Claims 38-48 ultimately depend from claim 37. As with claims 1 and 22, claim 37 recites that "after step a), all steps are performed without subsequent addition of any ingredients." Therefore, claim 37 is patentable over Myers for at

least the reasons discussed above with regard to claims 1 and 22. In addition, claim 37 recites at step b) "heat treating said solution at a temperature of from 60° to 75°C, for a time sufficient to permit denaturation of secondary structures without completely inactivating the reverse transcriptase and DNA polymerase activities of said enzyme system." Neither Sellner nor Shimomaye teach or suggest this feature.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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